

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 30, 31, 33 and 40-52 were examined and rejected.

By this Amendment, paragraphs 0039 and 0043 have been amended to correct for clerical errors, and claims 1-29 and 34-39 have been cancelled, claim 30 has been amended and claims 53-55 have been added.

Claims 1-29 and 34-39 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

The amendments to claim 30 were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to claim 30 and for newly added claims 53-55 is found in the originally filed claims and throughout the specification, in particular at the following exemplary locations: paragraphs 0041 and 0044-0046. Accordingly, no new matter is added by these amendments.

Claims 30, 31, 33 and 40-55 are pending after entry of the amendments set forth herein.

Applicants respectfully request entry of the amendments herein and reconsideration of the application in view of the amendments and remarks made herein.

**Rejections Under 35 U.S.C. §102**

Claims 30, 31, 33, 40, 41, 44, 45, 48 and 52 were rejected under 35 U.S.C. §102(e) as being anticipated by Yeshurun (U.S. Patent No. 6,558,361).

As amended, claim 30, as well as claims 31, 33, 40, 41, 44 and 45 by virtue of their dependency or chain of dependency on claim 30, provide a method of manufacturing a conical micro-needle structure having a lumen therein wherein the luminal axis and the structural axis intersect at an intersection angle. On the other hand, Yeshurun discloses a micro-needle structure having a lumen therein where the structural axis, i.e., cone-axis 32, and the luminal axis, i.e., bore-axis 30, are non-coincident and parallel to each other and therefore do not intersect each other. Further, Yeshurun does not teach or suggest a micro-needle structure other than one having a regular or non-oblique cone configuration.

Claims 48 and claim 52 by virtue of its dependence on claim 48 provide a method of manufacturing a micro-needle structure having an oblique cone configuration. On the other hand, Yeshurun only discloses a micro-needle structure having a regular or non-oblique cone configuration.

Further, Yeshurun does not teach or suggest a micro-needle structure other than one having a regular or non-oblique cone configuration.

Accordingly, Yeshurun does not anticipate claims 30, 31, 33, 40, 41, 44, 45, 48 and 52. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

**Rejections Under 35 U.S.C. §103**

Claims 42, 43, 46, 47, 49, 50 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yeshurun in view of Massau (U.S. Patent No. 4,838,877).

The Applicants respectfully submit that neither Yeshurun nor Massau alone or in combination teach or suggest all of the limitations of any of claims 42, 43, 46, 47, 49, 50 and 51. As discussed above, Yeshurun neither discloses, teaches or suggests a micro-needle structure having a lumen therein wherein the luminal axis and the structural axis intersect at an intersection angle (with respect to claims 42 and 43) nor a micro-needle structure other than one having a regular or non-oblique cone configuration (with respect to claims 46, 47, 49, 50 and 51).

With respect to claim 42, Massau fails to make up for the deficiencies of Yeshurun as Massau is cited solely for its teaching relating to use of polycarbonate as a suitable material for the microneedle. With respect to claims 43 and 46, Massau fails to make up for the deficiencies of Yeshurun as Massau is cited solely for its teaching relating to use of injection molding as a technique suitable for making the microneedle. With respect to claims 49 and 50, Massau fails to make up for the deficiencies of Yeshurun as Massau is cited solely for its teaching relating to a capsule or ampule for receiving and containing fluid. With respect to claim 51, Massau fails to make up for the deficiencies of Yeshurun as Massau is cited solely for its teaching relating to using a therapeutic agent.

Accordingly, for at least the reasons described above, the combination of Yeshurun and Massau fails to render claims 42, 43, 46, 47, 49, 50 and 51 obvious. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

**Newly Added Claims**

For at least the reasons discussed above, newly added claims 53-55 are not anticipated by or made obvious in view of either Yeshurun or Massau or the combination thereof.


**Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-024.

Respectfully submitted,  
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Date: 9/24/03

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